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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,265	GAITANARIS ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *655 and 658-662* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *655 and 658-662* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1) Claims 655 658 to 662 are pending in the instant application. Claims 661 and 662 have been amended and claims 643 to 654, 656, 657 and 663 to 675 have been canceled as requested by Applicant in the correspondence filed 12 February of 2008.

Election/Restrictions

2) Applicant's election without traverse of claims 655 and 658 to 662, drawn to a binding assay employing a protein identified in the specification as "GPR85", in the reply filed on 11 December of 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

3) The disclosure is objected to because pages 19 and 20 are missing therefrom. This material is also missing from the published version of the instant application, US 2006/0134109, where a gap in subject matter is found in the fifth from the last line in paragraph 0028 of that publication.

4) The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5) Applicant is that, upon an indication of allowable subject matter, Applicant will be required to modify the brief summary of the invention and to restrict the

descriptive matter so that they are confined to and in harmony with the invention to which the allowed claims are directed. See MPEP § 1302.01. For example, the text on pages 50 to 53 of the specification discusses lung disorders that have absolutely no bearing upon the currently claimed invention. In fact, the material presented in vast majority of the instant specification has not relationship to "GPR85" and neurological disease or disorders.

Drawings

6) The tables presented in Figures 1 to 4 of the instant specification do not comply with 37 C.F.R. 1.52 (c) with respect to font size. 37 C.F.R. 1.58 (c) states that:

> Chemical and mathematical formulae and tables must be presented in compliance with § 1.52(a) and (b), except that chemical and mathematical formulae or tables may be placed in a landscape orientation if they cannot be presented satisfactorily in a portrait orientation. Typewritten characters used in such formulae and tables must be chosen from a block (nonscript) type font or lettering style having capital letters which are at least 0.21 cm. (0.08 inch) high (e.g., elite type). A space at least 0.64 cm. (1/4 inch) high should be provided between complex formulae and tables and the text. Tables should have the lines and columns of data closely spaced to conserve space, consistent with a high degree of legibility.

Further, 37 C.F.R. 1.84(p)(3) requires that numbers, letters, and reference characters presented in a drawing must measure at least.32 cm. (1/8 inch) in height.

The corrected drawings are required in reply to the Office action to avoid abandonment of the application. **The requirement for corrected drawings will not be held in abeyance**.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7) Claims 655 and 658 to 662 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant claims are drawn to a method of identifying a compound that binds to, activates or inhibits the activity of a protein comprising the amino acid sequence presented in SEQ ID NO:552 of the instant application and identified in Table 2 on page 177 therein as "GPR85". Whereas the claims recite "[a] method for identifying a compound that may be useful for the treatment or prevention of a neurological disorder", there is insufficient evidence to establish a nexus between the activation or inhibition of "GPR85" and a desirable effect on a specific disease or disorder. The claims are drawn to a method that lacks a specific and substantial utility in currently available form because the instant application does not disclose an established specific biological role for "GPR85" or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

It is clear from the instant specification that the putative receptor protein described therein as "GPR85"is what is referred to as an "orphan receptor" in the art. This is a protein whose cDNA has been isolated because of it encodes an amino acid sequence that is similar to that of one or more known receptor proteins or putative receptor proteins. There is little doubt that, after complete characterization, a receptor protein of the instant invention may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it

has been undertaken Applicant's claimed invention is incomplete. While one could readily employ a putative receptor protein of the instant invention in an assay to identify ligands thereto the information obtained thereby would be of little use until one discovers the identity of those physiological processes moderated by the interaction of that ligand with that putative receptor. Whereas the instant specification discloses that the elimination of "GPR85" from mice has several substantial physiological consequences, as described on page 338 therein, such observations do not support a specific utility. One of ordinary skill in the art of receptor biology would reasonably predict that the elimination of any G protein-coupled receptor (GPCR), other than a sensory receptor such as an odorant or taste receptor, to have profound if not fatal consequences upon the mammal from which it has been eliminated. However, the fact that the elimination of "GPR85" has an effect upon the neurology of a mammal does not support the conclusion that any particular neurological disease or disorder is the consequence of an abnormal level of activity of "GPR85" in a mammal.

Because the instant specification has failed to credibly identify a physiological process which has been shown to be influenced by the activation or inhibition of a putative receptor protein of the instant invention an artisan has no way of predicting what effects the administration of a "GPC85" agonist or antagonist to an organism will have. Simply eliminating "GPR85" from a mammal provides little information with respect to the consequences of activating or inhibiting that receptor *in vivo* because it is well known in the art that the agonist activation of certain GPCRs produce a stimulatory response whereas the activation of other GPCRs produce an inhibitory response. For

example, it is old and well known in the art of GPCR biology that the D1 subtype of dopamine receptors stimulate adenylate cyclase upon agonist activation whereas the D2 subtype of dopamine receptors inhibit adenylate cyclase activity upon agonist activation. In addition, numerous GPCRs are known to have constitutive or basal activity, in which agonists stimulate that activity, inverse agonists cause a reduction in basal activity, and antagonists inhibit agonist-induced stimulation of receptor activity. Given the complex nature of GPCR activity, one can not determine from Applicant's results if the consequences observed by the deletion of "GPR85" from mice is the result of a loss of a stimulatory activity or the loss of an inhibitory activity. Therefore, one can not predict the physiological consequences of administering a "GPR85" agonist or antagonist to a mammal based upon the results described in the instant specification. If one can not predict the effects that the administration of an agonist or antagonist of a "GPR85" protein of the instant invention is going to have on an organism then it is unclear as to what practical benefit is derived by the public from the identification of that agonist or antagonist.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not

the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a method of identifying compounds that bind to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "GPR85" protein that is employed in the instant invention is associated in any way with any or all of the plurality of causally unrelated diseases and disorders that are listed, for example, on pages 7 to 18 of the instant specification. Further, there is no evidence of record that a knock-out mouse lacking "GPR85" is an accepted model for any known neurological disease or disorder. Until some actual and specific relationship has been established between the activity of the protein identified in the specification as "GPR85" and a specific neurological disease or disorder the instant invention is incomplete. To employ a "GPR85" protein of the instant invention in the identification of substances which inhibit or induce its activity in the absence of an established nexus between that activity and the pathology of a specific neurological disease or disorder is clearly to use "GPR85" as nothing more than the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability.

Since the instant specification does not disclose a credible "real world" role for “GPR85” in the pathology of a specific neurological disease or disorder then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8) Claims 655 and 658 to 662 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9) Claims 655 and 658 to 662 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite because the metes and bounds of the limitation “substantially identical” are undeterminable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10) Claims 655 and 658 to 662 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Elshourbagy et al. patent (6,071,722). The amino acid sequence presented in SEQ ID NO:2 of the Elshourbagy et al. patent is identical to SEQ ID NO:552 of the instant application. The text beginning in column 10 and continuing through column 13 of Elshourbagy et al. taught screening methods employing a protein of SEQ ID NO:2 in the identification of compounds that bind thereto as well as agonists and antagonists of that protein. The text in the last full paragraph in comumn 12 and the paragraph bridging columns 12 and 13 disclosed the utility of compounds that were identified by employing the screening methods taught therein in the treatment of a plurality of diseases, including diabetes, obesity, anorexia and schizophrenia, as recited in the instant claims. Every element of the instant claims was disclosed, either expressly or inherently, in the Elshourbagy et al. patent more than one year before the instant application was filed.

Applicant is advised that this rejection is not in conflict with the enablement rejection above. As stated in *Ex parte Dash*, 27 USPQ2d 1481 (BdPatApp&Int, 1993) "[w]e are not unaware that we are sustaining rejections under lack of enablement based on reasons which also apply to the prior art" and "[i]f appellants overcome the lack of enablement of their claims, they will necessarily overcome the lack of enablement of the references". All of the elements of the claimed invention were in the prior art. Further, the instant specification provides neither an element of predictability that was lacking from the prior art or the disclosure of unexpected results. In addition, whereas the prior art only needs to describe a single embodiment of the claimed invention in sufficient

detail as to permit one to make it in order to be anticipatory under 35 U.S.C. 102, the prior art does not have to disclose how to use the invention in a specific and substantial manner. The instant specification, however, is requires by the first paragraph of 35 U.S.C. 112 to disclose how to use the claimed invention in at least one credible specific and substantial manner. In other words, the prior art need not disclose a practical utility for the claimed invention to be anticipatory, but the instant specification does have to disclose such a utility to meet all of the requirements of the first paragraph of 35 U.S.C. 112.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649